

## **PSJ2 Exh 72**

**From:**  
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Dr. Robert F. Kaiko  
Vice President-Clinical Research  
Purdue Pharma L.P.  
One Stamford Forum  
Stamford, CT

Dear Dr. Kaiko,

I am following up on our conversation to ask Purdue Pharma for grant support to continue and broaden the international work of the Pain & Policy Studies Group (PPSG) to improve the policy and regulatory climate for pain management and the use of opioid analgesics.

First, I want to express our sincere appreciation for the international support that has been provided by Purdue Pharma for the last several years. Without your support, some of the progress reported below would not have been possible.

As you know, the PPSG is also a Collaborating Center with the World Health Organization (WHO). In recent years, we have been the catalyst in making pain policy part of the larger field of pain management and palliative care in the world. Our small group is actively and systematically engaged in improving international and national pain policy, using an approach to regulatory barriers patterned after the medical model of diagnosis, treatment and evaluation that shows measurable results. We are always available for rapid consultation and technical assistance. As a Collaborating Center, we develop models, sponsor international projects and maintain liaison with international organizations, including the International Narcotics Control Board and the WHO. Information about our work around the world is available in our annual reports, the most recent of which is for 2001 which are available at <http://www.medsch.wisc.edu/painpolicy/publicat/annrepts.htm>

A summary of our recent international work is provided below. The feedback we receive about our work and publications has been excellent but there is a long way to go. I am not aware of any other group in the world with this focus or track record. Although we want to continue this work, we receive little support from the University and WHO, and must rely on the generosity of those who understand the value of our work. I would like to request an unrestricted educational grant to support our international program in the amount of \$175,000 for this year, renewable for two more years.

Our objectives for the future are to:

- Increase visibility of the inadequate treatment of pain and unavailability of opioid analgesics in most of the world
- Continue to serve as a pain policy resource for experts and various initiatives around the world aimed at improving the regulatory environment for pain management
- Provide education about how the drug control system is intended to ensure patient access to opioid medications
- Put WHO Guidelines for Achieving Balance into action, including through follow up and implementation of action plans for 17 countries in Africa, Eastern Europe, and selected countries in Latin America including Mexico; publish results
- Use publications such as the *European Journal of Cancer Care* article about Italy and our publications in the *Lancet* and *Journal of Pain and Symptom Management* about India to increase visibility of the need to achieve balanced national policies
- Consider ways to improve cooperation between government narcotic regulators and national pain management "Champions"
- Participate in activities of the WHO and the International Narcotics Control Board
- Expand the resources on our website to include other languages, especially Spanish

I hope the international work highlighted below is sufficient to convince Purdue Pharma to continue and expand its support of the international activities of the PPSG. I would be happy to meet with you to provide further information and respond to any questions. I look forward to hearing from you.

Sincere regards,

David E. Joranson  
Senior Scientist, Director  
Pain & Policy Studies Group  
WHO Collaborating Center  
University of Wisconsin

1-WHO Guidelines for achieving balance. We proposed to the WHO that we could prepare first-of-a-kind WHO guidelines for use in evaluating national narcotics laws to determine if they have the elements necessary to ensure adequate availability of opioid analgesics for patient care while at the same time recognizing the safety issues and taking adequate measures to prevent diversion. The WHO contracted with us, we prepared the Guidelines and hosted an international delegation of pain and regulatory experts to review the draft; WHO published the Guidelines in 2000; they were endorsed by the INCB. This document now serves as strong and clear guidance for national regulators to work with health professionals to ensure availability of pain medications throughout the world. See <http://www.medsch.wisc.edu/painpolicy/publicat/00whoabi/00whoabi.htm>. The Guidelines have been translated into French, Italian and Spanish and are available via our website. Since 2000, I have presented the Guidelines to regulators in China, to other government regulators all over Asia through annual talks to seminars sponsored by the Japanese government in Tokyo, and to governments in Africa, Latin America and Europe.

2-Put WHO Guidelines into action. We began implementing the new WHO guidelines in 2000 by working with WHO and its regional offices to convene workshops of representatives of government and non government organizations from each country to review the guidelines and develop action plans. The participants include representatives of narcotics control, cancer, AIDS, pain and palliative care. We now have action plans (that need to be implemented) for 17 countries: 6 countries in Latin America (Bolivia, Chile, Colombia, Ecuador, Peru, Venezuela), 6 countries in Eastern Europe (Bulgaria, Croatia, Hungary, Lithuania, Poland, Romania), and 5 countries in Africa (Botswana, Ethiopia, Tanzania, Uganda, Zimbabwe). An example of the situation in Africa is available at <http://www.medsch.wisc.edu/painpolicy/publicat/monograp/afrom orph.doc>. The action plans spell out the steps necessary to address regulatory barriers to greater availability and patient access to opioid analgesics. As an example of progress in Latin America, the action plan for Peru identified as a barrier the national law that restricted outpatient prescriptions of opioids such as morphine to a 24 hour supply. This law has now been changed to permit a 15 days' supply.

3-Educate about unavailability of opioid analgesics. We use the opportunity of workshops and international meetings to educate regulators and health professionals about the unavailability of opioid analgesics, by providing monographs and slide presentations that depict the trends and patterns of opioid use in the world and in selected countries. Examples of these monographs may be found at <http://www.medsch.wisc.edu/painpolicy/publicat/monograp/globaltrends.htm>

4-Increase patient access and use of opioid analgesics while monitoring misuse and diversion. We have developed and successfully tested a model to demonstrate that it is possible in a developing country like India to ensure consistent availability of morphine to patients. Our research article in the *Lancet* showed that this was accomplished with no evidence of misuse or diversion. We caution that if diversion does occur, the response should be to identify and address the specific source of diversion without interfering in legitimate medical practice and patient care. The *Lancet* article is available on our website at <http://www.medsch.wisc.edu/painpolicy/publicat/01lancet/contents.htm>. The second report on our project to simplify the narcotic regulations and increase morphine use in India was just published in the *Journal of Pain and Symptom Management* (August, 2002). This article is also available on our website at: <http://www.medsch.wisc.edu/painpolicy/publicat/02jpsm3/index.htm>

5-Reform national policies. Using the WHO Guidelines, we provided considerable assistance to the Italian authorities who have now revised their national narcotics control policy to simplify the terribly complex prescription requirements and eliminate some of the quantity limitations that have been responsible for the Italy being one of the lowest per capita consumers of opioids in Europe. We provided technical assistance to a pain specialist and member of a national commission to revise the Italian drug laws, Dr Claudio Blengini; we also provided video testimony to the Minister of Health; please see <http://www.medsch.wisc.edu/painpolicy/publicat/monograp/italy2000.rtf>. An article reporting this work will be published early in 2003 in the *European Journal of Cancer Care*. We have also provided technical assistance to health professionals and governments in China, Malaysia, Indonesia.

6-Communicate. In addition to our commitment to publish the results of our work, we manage a communications program designed to systematically disseminate our work products via notification to a national and international audience using a large and growing email list. Each notification includes a direct link to the product on our website. The extensive international section of our website provides access to a number of key resources. In addition, we provide presentations to international meetings, including recent meetings of the 1st Latin American Congress on Palliative Care in Guadalajara, Mexico and the International Association for the Study of Pain in San Diego. The powerpoint presentation that was used in Mexico is available at this link: <http://www.medsch.wisc.edu/painpolicy/publicat/monograp/GDLMex-span/sli de1.htm>